DEC 16 2005 K053256 page 1 of 2

Premarket Notification Summary

- **Sponsor Information:**

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Amy E. Short
Regulatory Manager

Phone Number: (651) 737-6707
FAX Number: (651) 737-5320

- **Device Name:**

Common or Usual Name: Silver Dressing

Proprietary Name: 3M™ Tegaderm™ Silver Nonwoven Dressing
Also called 3M™ Tegaderm™ Ag Mesh Dressing with Silver

Classification Name: Unclassified

- **Predicate Device:**

3M™ Tegaderm™ Silver Nonwoven Dressing has predicates 3M™ Tegaderm™ Silver Nonwoven Dressing (K040890) and Acticoat™ Silver Coated Dressing, aka Acticoat™ Burn Antimicrobial Dressing, manufactured by Smith & Nephew (originally cleared under K955453).

- **Description of Device:**

3M™ Tegaderm™ Silver Nonwoven Dressing is a nonwoven dressing that contains (8 mg/gm of dressing) of silver sulfate. Silver ions released from the silver sulfate create an effective barrier. The soft, absorbent dressing is supplied sterile and may be custom cut to fit the wound. The porous, non-occlusive dressing conforms to the wound base and wicks drainage into the dressing where *in vitro* studies show that the silver ions may reduce the number of microorganisms, including bacteria and yeast.

- **Indications for Use:**

  3M™ Tegaderm™ Silver Nonwoven Dressing is indicated for use as a primary wound dressing over:

- abrasions
- ulcers
- trauma wounds
- surgical wounds
- first and second degree burns
- donor sites,

- **Description of Safety and Substantial Equivalence:**

  Safety Studies – A standard battery of biocompatibility studies was conducted: Cytotoxicity, Intracutaneous Irritation in rabbits, and Skin Sensitization in guinea pigs. No deleterious effects were observed with 3M™ Tegaderm™ Silver Nonwoven Dressing ; results were comparable to or better than those reported for Acticoat™ Silver Coated Dressing. The results are those presented for the previously cleared device, 3M™ Tegaderm™ Silver Nonwoven Dressing, (K040890).

  Effectiveness – 3M™ Tegaderm™ Silver Nonwoven Dressing was compared with Acticoat™ Silver Coated Dressing in *in vitro* reduction studies against a known number of microorganisms, such as gram-negative and gram-positive bacteria and yeast (*Candida albicans*). The results of this study demonstrated that 3M™ Tegaderm™ Silver Nonwoven Dressing was substantially equivalent to Acticoat™ Silver Coated Dressing effectiveness. The results are those presented for 3M™ Tegaderm™ Silver Nonwoven Dressing (K040890)

  Substantial Equivalence – 3M™ Tegaderm™ Silver Nonwoven Dressing with modified label, the previously cleared device (K040890) and Acticoat Silver Coated Dressing (aka, Acticoat™ Burn Antimicrobial Dressing) provide the same function and have the same indications for use. These characteristics, as well as the results of safety studies and effectiveness show the two products to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Amy E. Short
Regulatory Manager
3M Health Care
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K053256
Trade/Device Name: 3M™ Tegadrem™ Silver Nonwoven Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 21, 2005
Received: November 22, 2005

Dear Ms. Short:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucholo
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K053256

Device Name: 3M™ Tegaderm™ Silver Nonwoven Dressing, also called 3M™ Tegaderm™ Ag Mesh Dressing with Silver

Indications for Use:

3M™ Tegaderm™ Silver Nonwoven Dressing is indicated for use as a primary dressing over:

- abrasions
- ulcers
- trauma wounds
- surgical wounds
- first and second degree burns
- donor sites

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MPM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053256